DSJ1&2-PR Exh 581

Message

From: Dymon, Christopher [christopher.dymon@walgreens.com]
Sent: 1/21/2013 3:31:14 PM
To: Daugherty, Patricia [patricia.daugherty@walgreens.com]
Subject: FW: TD GFD Parameters ppt
Attachments: TD GFD Parameters_webinar for PILOT.pptx

Be Well,
Chris

Christopher Dymon, PharmD
Manager - Pharmaceutical Integrity
Walgreen Co.
200 Wilmot Road, MS 2194
Deerfield, IL 60015
P: 847-315-2693

From: Polster, Tasha
Sent: Monday, January 21, 2013 10:16 AM
To: Dymon, Christopher
Subject: TD GFD Parameters ppt

Be well,
Tasha

Tasha Polster, RPh
Director, Pharmaceutical Integrity
Walgreen Co
847 315 3379

Every day I help people **get, stay and live well.**

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Target Drug (TD)
Good Faith Dispensing (GFD)
Parameters Pilot
Tasha Polster
Director, Pharmaceutical Integrity
November 2012
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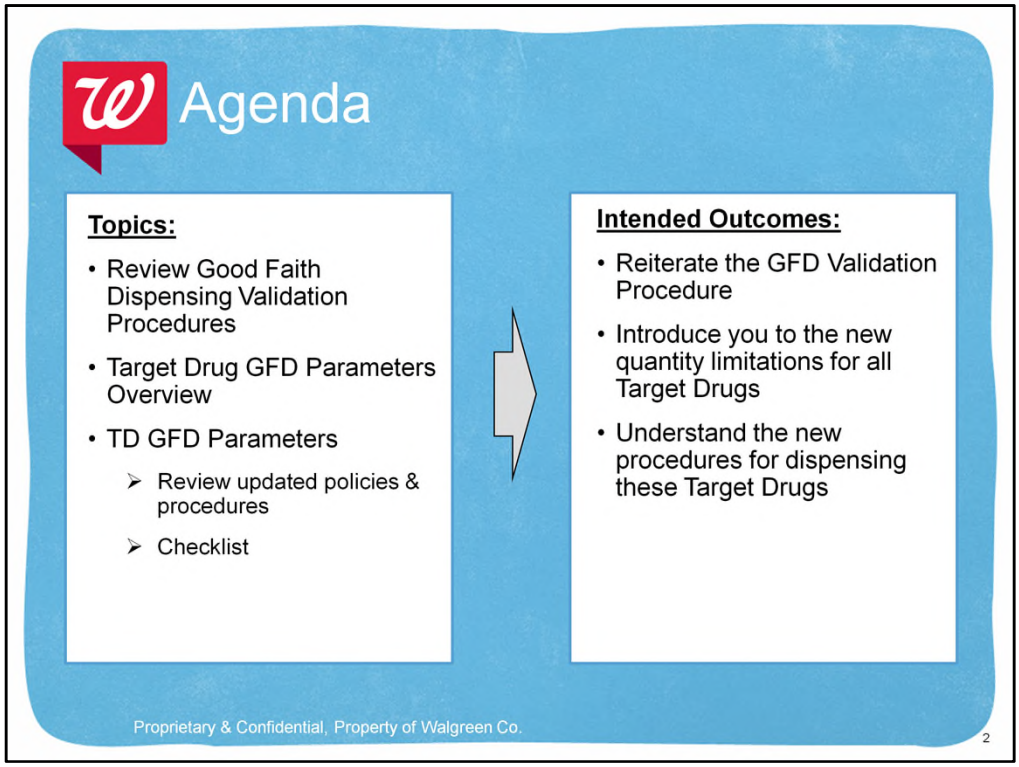
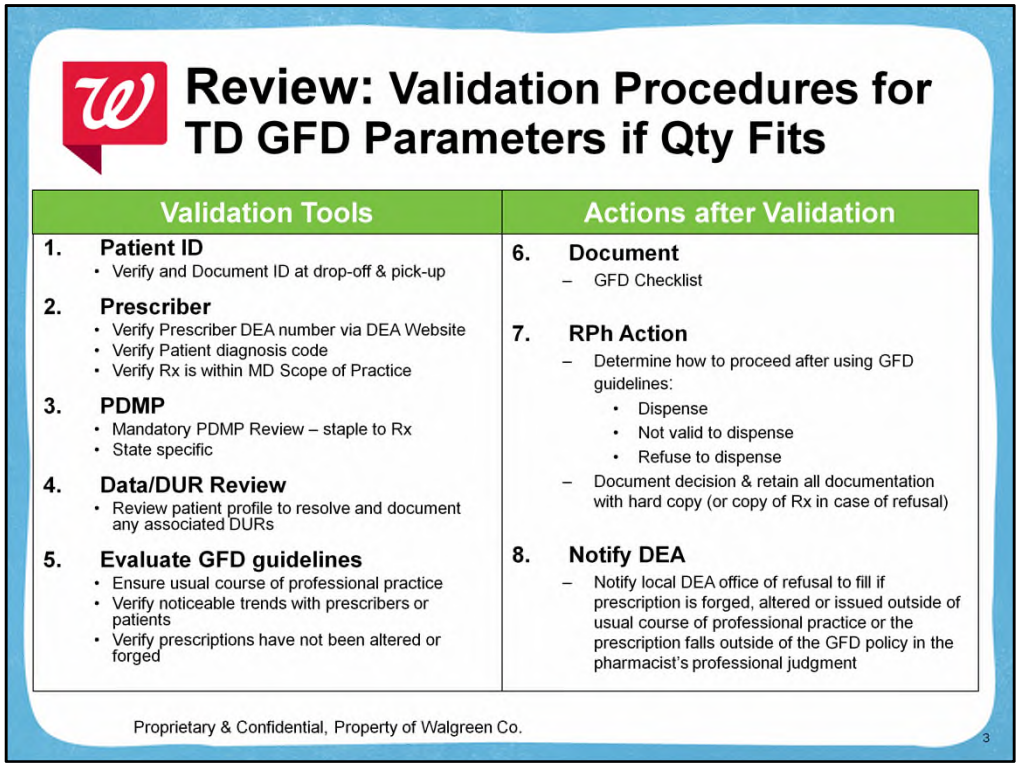


We'll start with a quick review of the GFD policy and then go into the new Target Drug GFD.



Let's review the updated validation procedures contained in the TD Good Faith Dispensing Policy. For the single entity TD of Oxycodone, Hydromorphone and methadone; if the prescription is being paid for by cash, the prescription cannot be for a quantity larger than 60. If the prescription is being billed to a 3rd party, the prescription cannot be written for a quantity greater than 120. If the parameter is not met, hand the prescription back to the patient and tell them "I am sorry but Walgreens no longer fills prescriptions for this medication for these large quantities. It cannot be filled here or at any Walgreens."

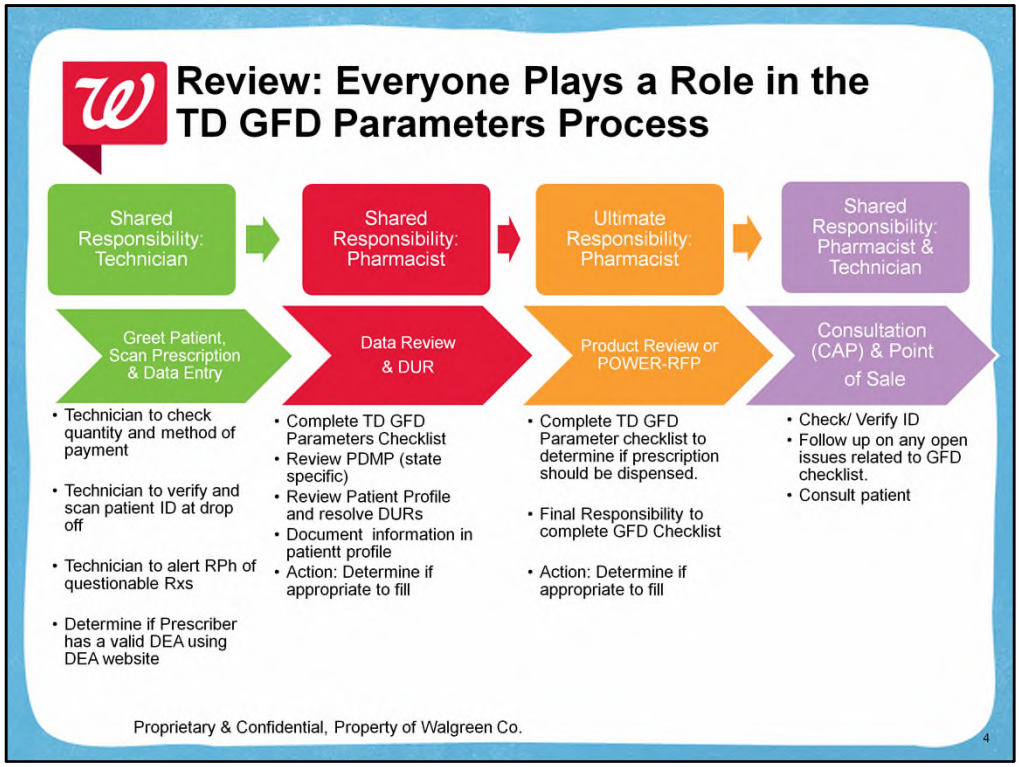
Review the validation steps:

The first 5 steps describe how pharmacy team members are able to determine the validity of a prescription. The last 3 are actions that should be completed after the initial validation steps. Every situation will not be the same. In some circumstances, you will use all GFD tools, however in other situations you may only need to use a few. We expect our pharmacists to use their professional judgment when dispensing controls and document accordingly.

If the TD prescription is written for a quantity within the parameters, Pharmacists shall use their professional judgment when determining if the elements of good faith are present prior to dispensing controlled substance prescriptions.

Please emphasize: The prescription must be valid and meet the elements of Good Faith for the prescription to be dispensed or the pharmacist should refuse to fill. Proper documentation is required. The local DEA office must be faxed within two business days for any refusals to fill. (Point 6, 7 and 8).

It is important that store leadership supports our pharmacists who make appropriate good faith dispensing decisions.



Now that we understand the validation steps for TD GFD Parameters, here is how everyone plays a role in the process.

Everyone in the pharmacy has a role in ensuring that the elements of Good Faith Dispensing are met. While all pharmacists and technicians have an obligation to assist with validation of Good Faith Dispensing requirements during the dispensing process, the **Product Review/RFP (Retail Fill Process) Pharmacist** has the ***ultimate responsibility*** for ensuring that the elements of Good Faith are present.

During the Product Review/RFP process, the pharmacist is attesting not only that the product is correct but also that Good Faith Dispensing guidelines have been validated and documented appropriately. The goal is that all elements of Good Faith Dispensing have been validated **before** getting to the Product Review/RFP Pharmacist. The Product Review/RFP Pharmacist should then be able to confirm the elements of Good Faith Dispensing have been met and continue with the dispensing process.

The goal is to have all elements of GFD confirmed throughout the filling process and prior to reaching the Product Review/RFP pharmacist.

POWER: Only a pharmacist should perform the RFP process for C-II's. Technicians should **not** perform RFP on CIIs and must pass to a pharmacist to complete the RFP process.

Why are we doing this?

- The practice of pharmacy is changing and it is not enough to just put the right pill in the right bottle for the right patient.
- Walgreens wants to ensure that our patients continue to have access to the medications they need and are serious about our role in reducing abuse of controlled substances, while we do everything we can to help reduce the abuse of controlled pain medications

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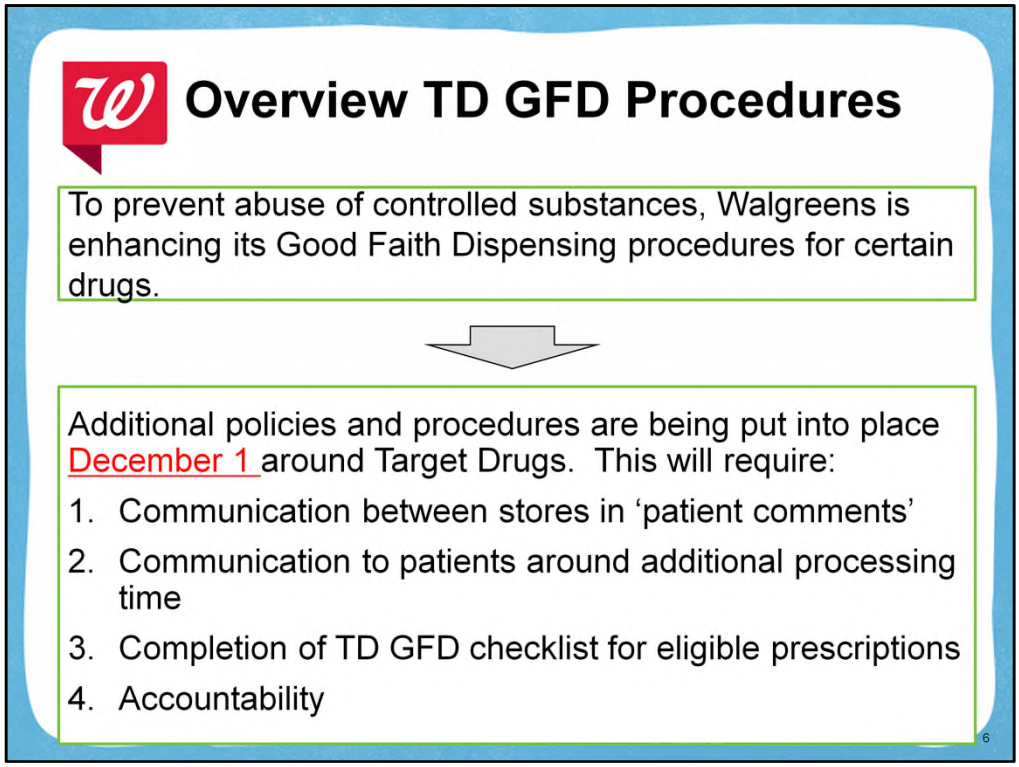
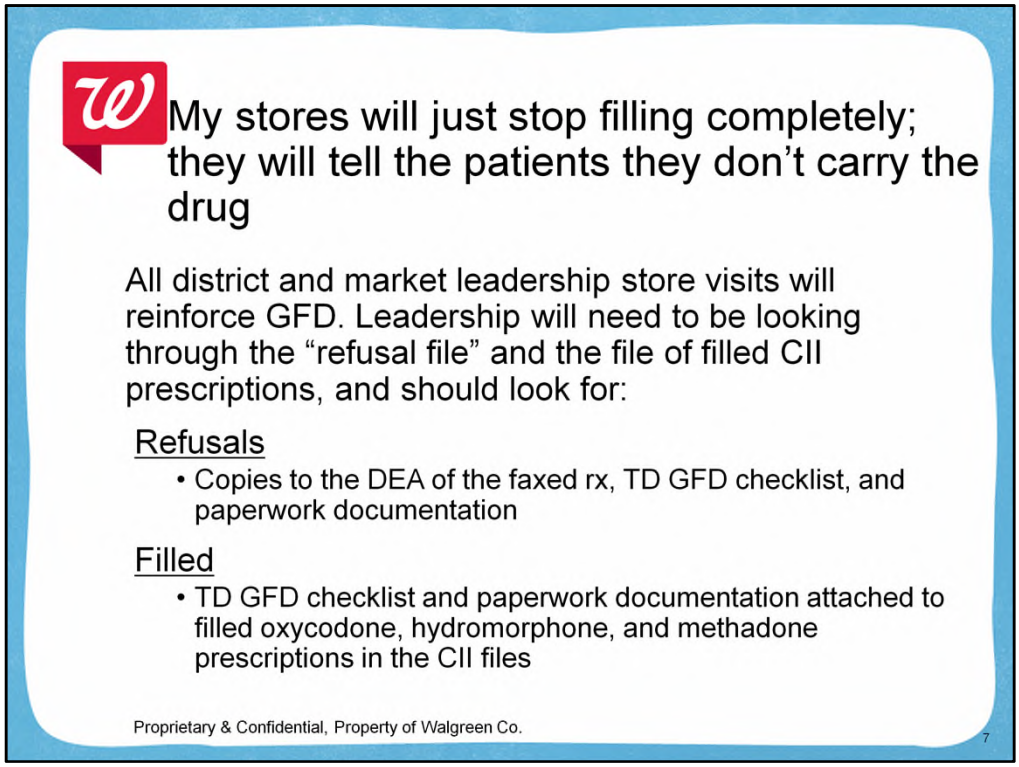


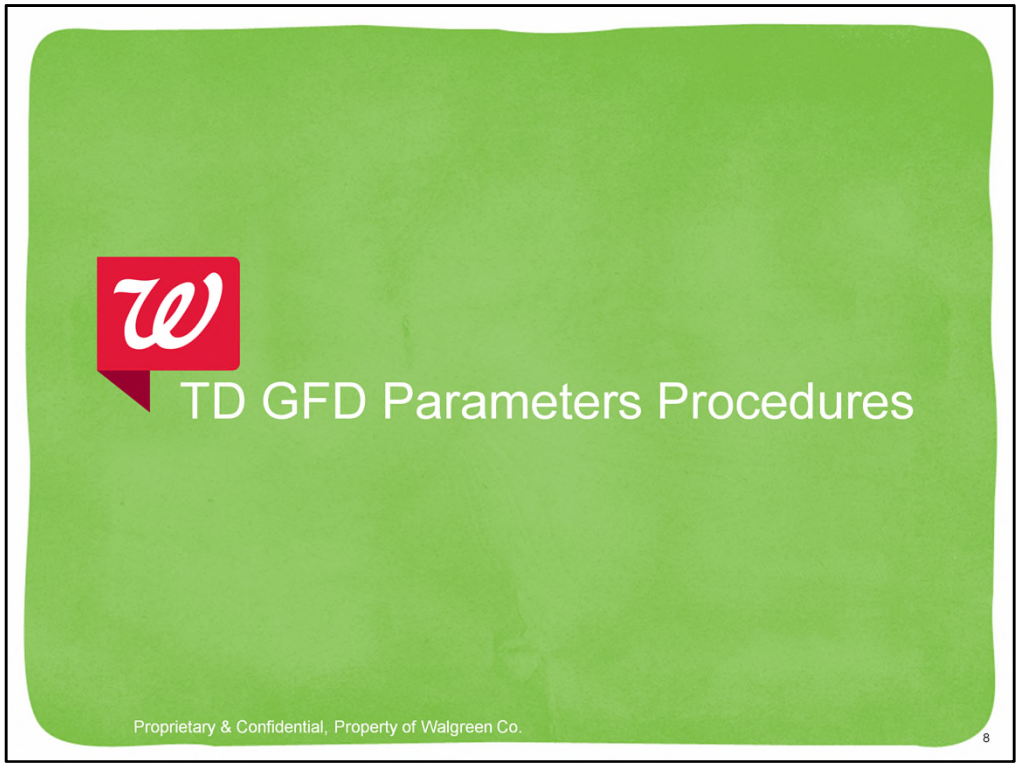
Additional processes are being put into place to protect our pharmacists and the company. The GFDP that you learned about over the summer has been updated to include dispensing practices that are uniform from store to store. This new policy was put into place in order to put a more rigorous and consistent process together in dispensing these Target Drugs. What we don't want to have happen is a prescription is refused at one Walgreen location only to be filled down the street at the next Walgreen location.

The target drugs we are going to begin with are the single entity Oxycodone, Hydromorphone and Methadone. With these products additional steps will need to be taken by the pharmacy staff.

Stores will be required to document in the patient comments that the prescription was filled or denied.
Patients will be required to give the pharmacy additional processing time to allow for the additional steps to be completed
TD GFD checklist will be required for every oxy, hydromorphone, methadone prescription
Failure to comply will lead to disciplinary action up to and including termination



It is unlikely that a full time pharmacist at that store would not dispense or refuse even one of these medications during the time between your visits to the stores. As district/market leaders, you will need to play an active role during your supervision visits to reinforce GFD and to ensure that the TD GFD is being followed.


TD GFD Parameters Procedures
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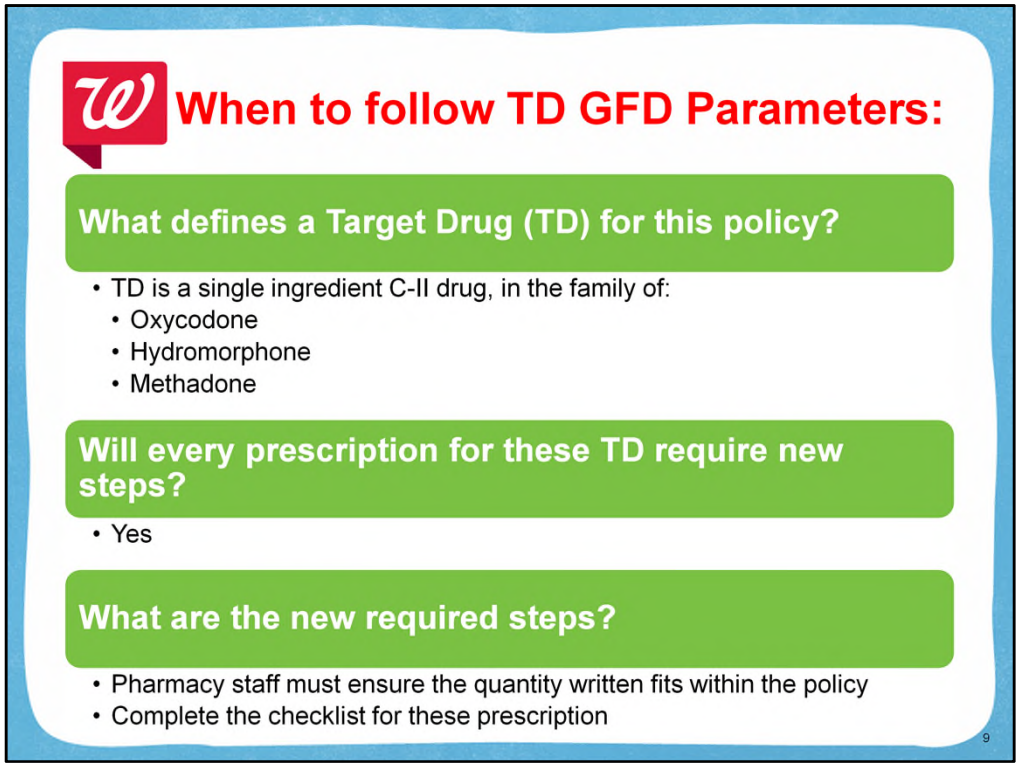
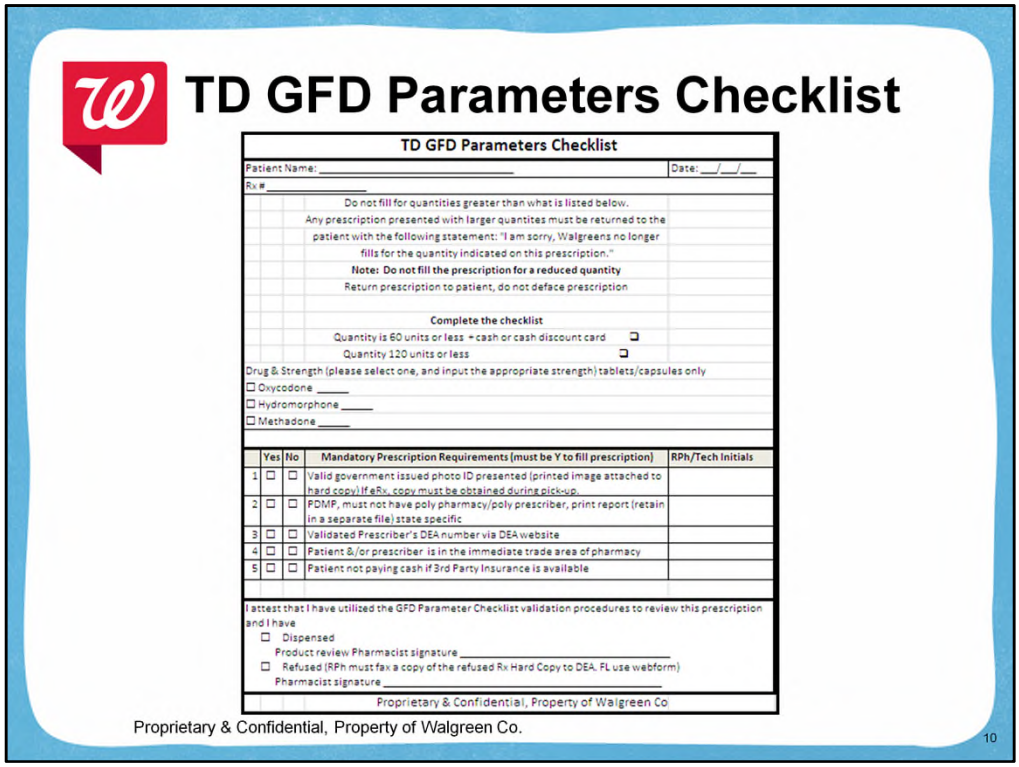


For this policy we are targeting just the single ingredient Oxy, Hydromorphone and Methadone (brand and generics) products. Every prescription for these medications will require these new parameters. No prescriptions written for quantities greater than 120 if paid for by 3rd party, or 60 if paid for by cash or a cash discount card will be filled. The TD GFD Parameters checklist will need to be completed, attached to the prescription or the refusal copy and a message will need to be entered into the patient's comment. Additionally, any refused prescription must be faxed to the DEA and the documentation of such action retained in the "refusal folder".

If a prescription does not meet the quantity parameter, hand the prescription back so the patient can take it elsewhere. If the prescription is written with the proper quantity to fit the parameter and does not meet GFD, fax the prescription to the DEA per GFD guidelines.



TD GFD Parameters Checklist

TD GFD Parameters Checklist

Patient Name: _____ Date: __/__/__

Rx # _____

Do not fill for quantities greater than what is listed below.
Any prescription presented with larger quantites must be returned to the patient with the following statement: "I am sorry, Walgreens no longer fills for the quantity indicated on this prescription."
Note: Do not fill the prescription for a reduced quantity
Return prescription to patient, do not deface prescription

Complete the checklist

Quantity is 60 units or less +cash or cash discount card ❑
Quantity 120 units or less ❑

Drug & Strength (please select one, and input the appropriate strength) tablets/capsules only

☐ Oxycodone _____
☐ Hydromorphone _____
☐ Methadone _____

	Yes	No	Mandatory Prescription Requirements (must be Y to fill prescription)	RPh/Tech Initials
1	☐	☐	Valid government issued photo ID presented (printed image attached to hard copy) If eRx, copy must be obtained during pick-up.	
2	☐	☐	PDMP, must not have poly pharmacy/poly prescriber, print report (retain in a separate file) state specific	
3	☐	☐	Validated Prescriber's DEA number via DEA website	
4	☐	☐	Patient &/or prescriber is in the immediate trade area of pharmacy	
5	☐	☐	Patient not paying cash if 3rd Party Insurance is available	

I attest that I have utilized the GFD Parameter Checklist validation procedures to review this prescription and I have

☐ Dispensed
Product review Pharmacist signature _____
☐ Refused (RPh must fax a copy of the refused Rx Hard Copy to DEA, FL use webform)
Pharmacist signature _____

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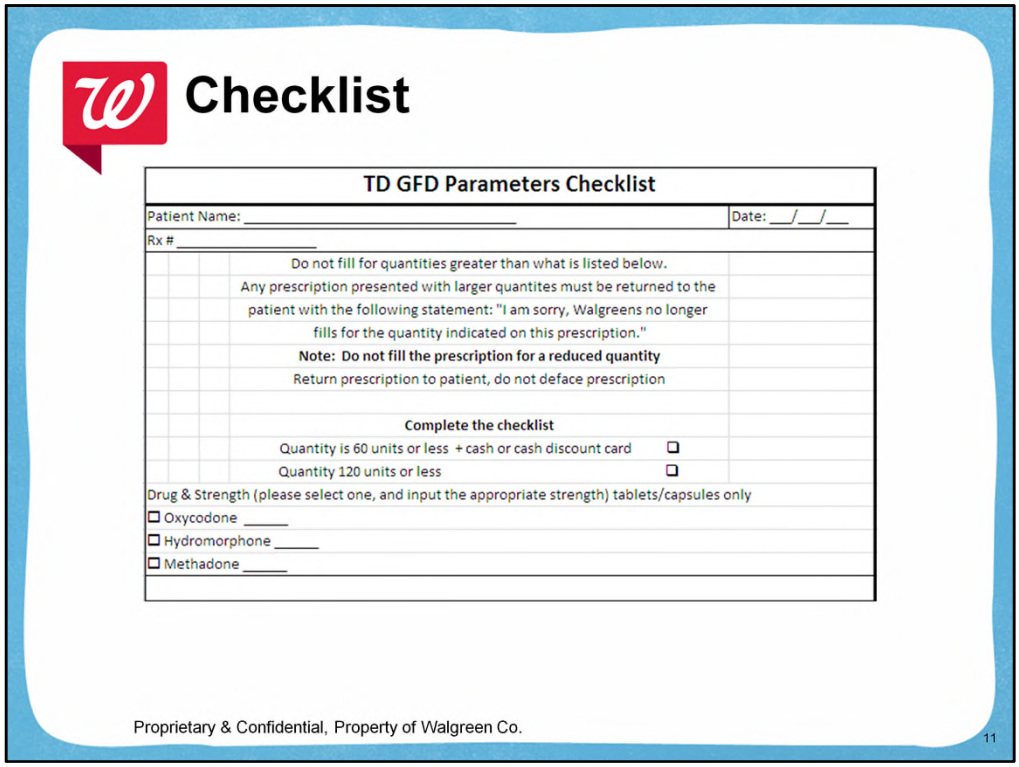
Checklist will be posted on SNet, stores will need to print out copies to have ready to use.



Checklist

TD GFD Parameters Checklist	
Patient Name: _____	Date: __/__/__
Rx # _____	
Do not fill for quantities greater than what is listed below.	
Any prescription presented with larger quantites must be returned to the	
patient with the following statement: "I am sorry, Walgreens no longer	
fills for the quantity indicated on this prescription."	
Note: Do not fill the prescription for a reduced quantity	
Return prescription to patient, do not deface prescription	
Complete the checklist	
Quantity is 60 units or less + cash or cash discount card ❑	
Quantity 120 units or less ❑	
Drug & Strength (please select one, and input the appropriate strength) tablets/capsules only	
❑ Oxycodone _____	
❑ Hydromorphone _____	
❑ Methadone _____	

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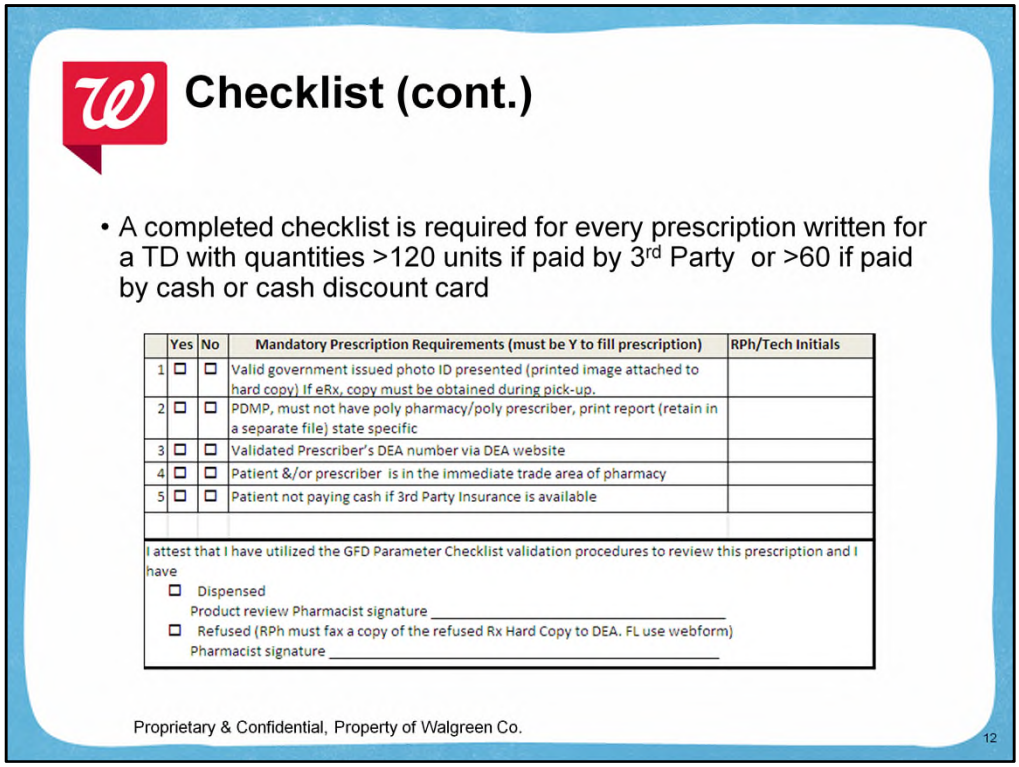
No prescription can be accepted for quantities larger than what is indicated on the checklist.



Checklist (cont.)

- A completed checklist is required for every prescription written for a TD with quantities >120 units if paid by 3rd Party or >60 if paid by cash or cash discount card

	Yes	No	Mandatory Prescription Requirements (must be Y to fill prescription)	RPh/Tech Initials
1	☐	☐	Valid government issued photo ID presented (printed image attached to hard copy) If eRx, copy must be obtained during pick-up.	
2	☐	☐	PDMP, must not have poly pharmacy/poly prescriber, print report (retain in a separate file) state specific	
3	☐	☐	Validated Prescriber's DEA number via DEA website	
4	☐	☐	Patient &/or prescriber is in the immediate trade area of pharmacy	
5	☐	☐	Patient not paying cash if 3rd Party Insurance is available	

I attest that I have utilized the GFD Parameter Checklist validation procedures to review this prescription and I have

☐ Dispensed
Product review Pharmacist signature _____

☐ Refused (RPh must fax a copy of the refused Rx Hard Copy to DEA. FL use webform)
Pharmacist signature _____

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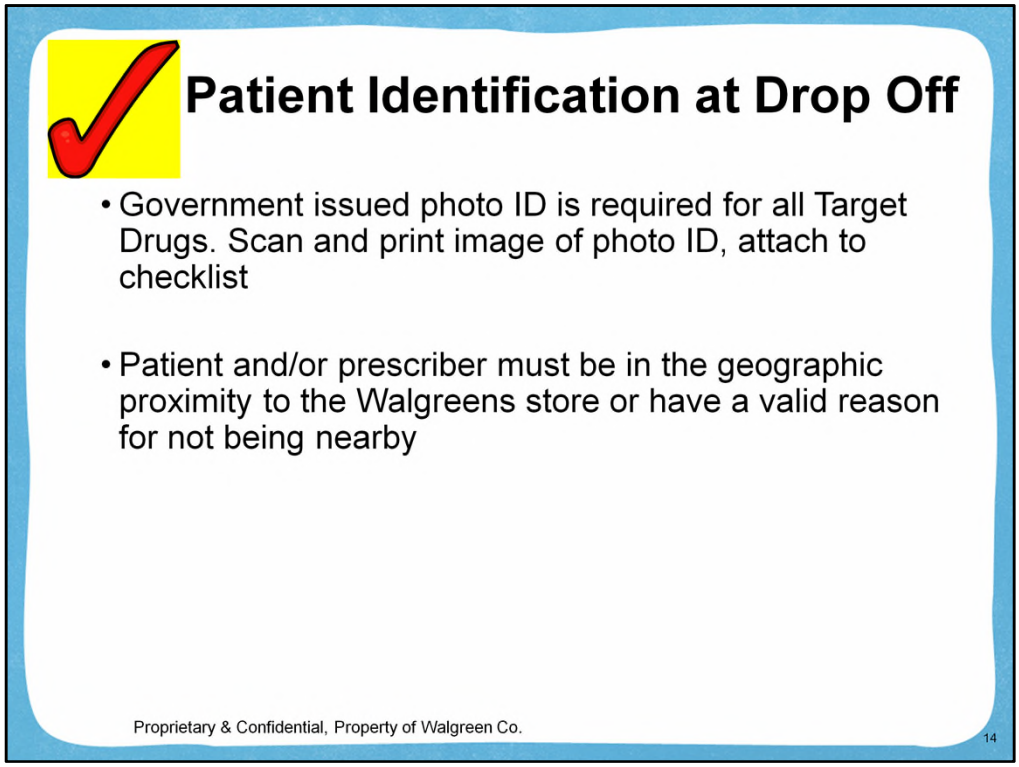
Calls to the prescriber are required for every patient per prescriber and target drug. We know these calls may be uncomfortable and unwelcome, so we have put together some tools to help the pharmacists. Prescriber talking points have been provided as well as a Pain Management document. That document was put together by our CMO office and has clinical information that the pharmacists may find helpful around pain management.

There will need to be documentation for both filled and refused prescriptions in the store. The market and district leadership will be looking for this on store visits.

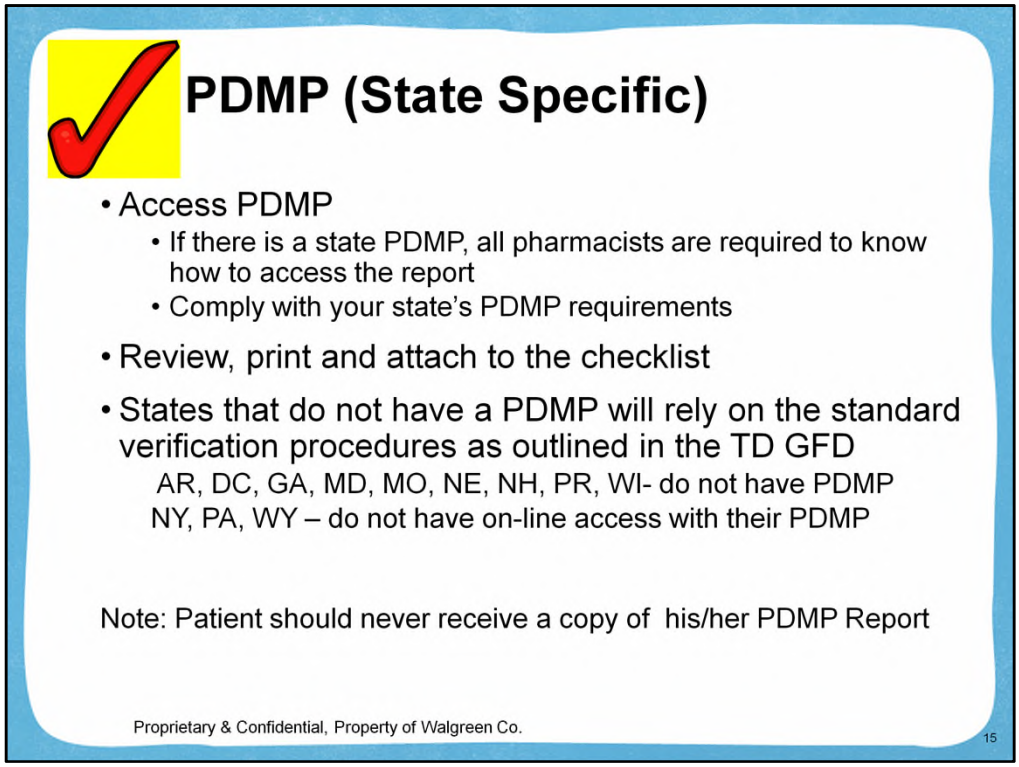
It is going to be okay for a pharmacist to refuse to fill a prescription based on the elements of the checklist and their professional judgment. And they need to know they have both corporate and leadership's support on this. However, they cannot just tell the patients that they are out of stock or they don't fill for this drug.

How will you know, you ask? It would be unlikely that a full-time RPh at a store would not fill/refuse any of these products in the amount of time between your store visits. When you look through the files, there should be documentation from each RPH that works at that location. We will need full support of RXS, DM and if you'd like to roll down to CL level, on this. GFD should be part of each supervision visit.



So, here is how it's going to look in the store, if the prescription is written for the appropriate quantity, the tech gets accepts the rx and they will request a photo ID which they will scan and print a copy of.

If the quantity does not meet the parameters, the prescription is to be returned to the patient with "I am sorry, Walgreens no longer fills prescriptions for this medication for large quantities."



Mandatory use of the PDMP website is required where PDMP is available. Every pharmacist must know how to access the PDMP and print a report for every TD prescription by patient

Prescriber Validation

- Confirm Prescriber's DEA license is valid/active via DEA website (https://www.deadiversion.usdoj.gov/webforms/validateLogin.jsp)
- Verify patient and/or prescriber address is within the geographic area.

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Dispensing and Selling TD Prescriptions

- If all points of the checklist are complete, the pharmacist can sign at the bottom and continue product review
- Attach the checklist and all documentation to the hard copy

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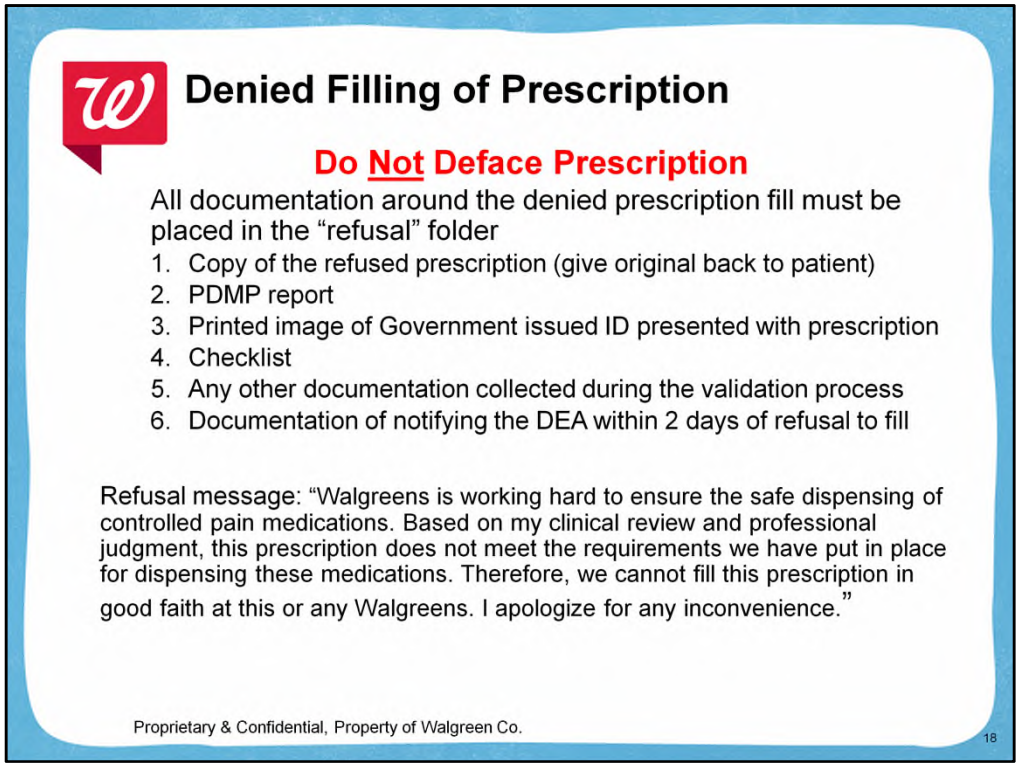

If the quantity meets the parameter guidelines for the policy, but the prescription does not meet GFD it is very important that the pharmacy staff not deface the prescriptions that they refuse to fill. Writing comments like "doctor under investigation" or other slanderous memos are not authorized. It is going to be a delicate situation as well, because there may be times where it is difficult to tell the legitimate pain patient, therefore delivering the refusal message is very important.

"Walgreens is working hard to ensure the safe dispensing of controlled pain medications. Based on my clinical review and professional judgment, this prescription does not meet the requirements we have put in place for dispensing these medications. Therefore, we cannot fill this prescription in good faith. I apologize for any inconvenience."

Accountability

An incident is defined as any failure to comply with the GFD and TD GFD policies and procedures. In cases of serious misconduct, it may be necessary to escalate to a higher level of discipline in this process, up to and including termination.

- **Step 1 (VERBAL COUNSELING)**
  - Review GFD policy and procedures with the pharmacist
  - Review the TD GFD Parameters policy and procedures with the pharmacist
  - Review GFD and TD GFD Parameters training materials (powerpoint, policies/procedures)
- **Step 2 (WRITTEN WARNING)**
  - Issue written warning to pharmacist
  - Re-assign and acknowledge the GFD
  - Review GFD and TD GFD Parameters training materials (powerpoint, policies/procedures)
  - Use the GFD and TD GFD Parameters training materials to develop an action plan for compliance with the GFD process
- **Step 3 (FINAL WRITTEN WARNING)**
  - DM and RXS to Issue the final written warning to the pharmacist
  - The pharmacist should be suspended for one work week coinciding with the pay week and be moved from his/her current location
- **Step 4 (TERMINATION)**

**Discipline is active for a rolling 12-month period from the date the discipline is issued to a team member. If more than 12 months have elapsed since issuance of discipline, repeat the prior discipline step.*

All documentation related to GFD discipline process must be entered into the Talent Management Portal as discipline for misconduct.

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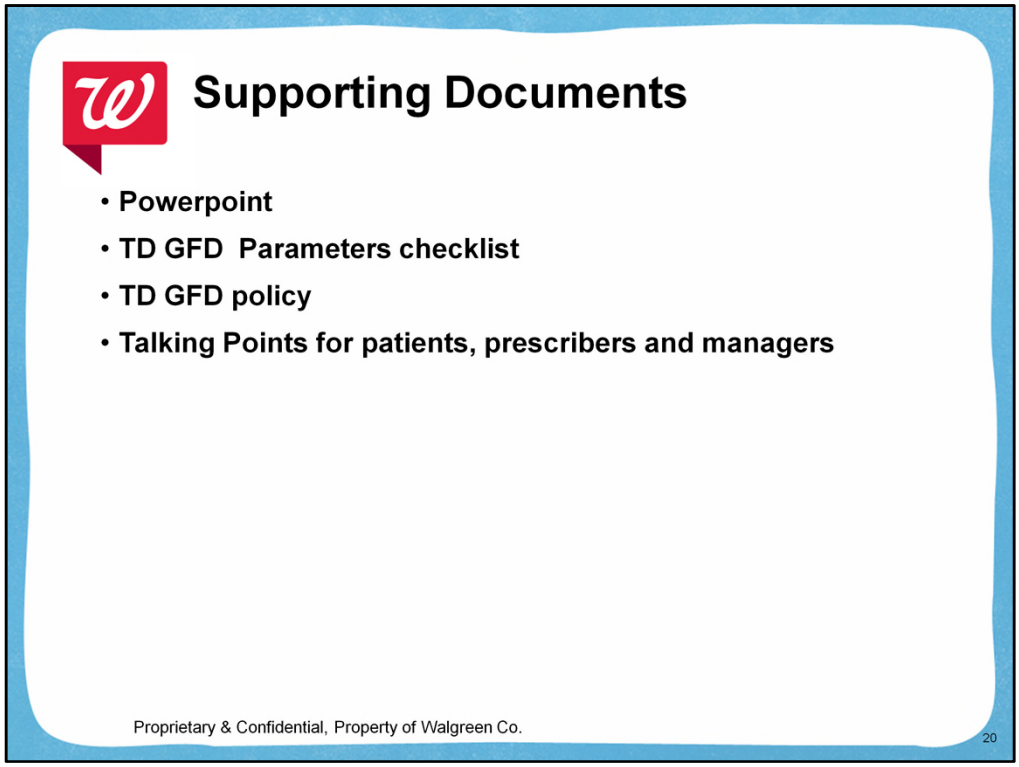
Supporting Documents
• Powerpoint
• TD GFD Parameters checklist
• TD GFD policy
• Talking Points for patients, prescribers and managers
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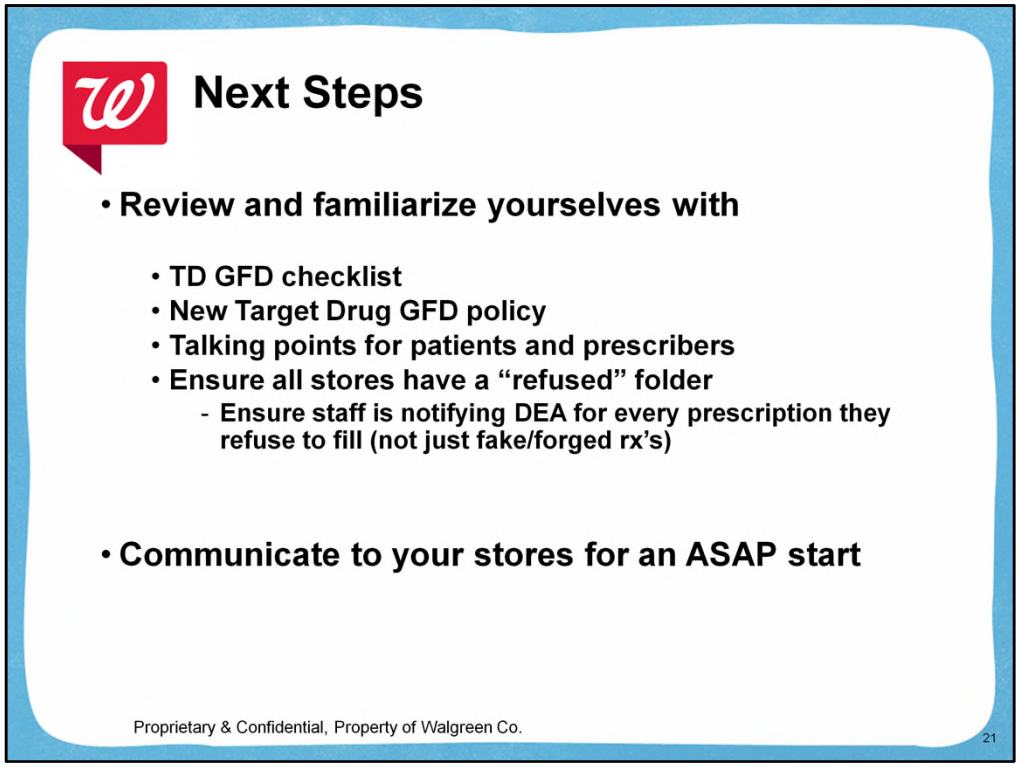
Next Steps
• Review and familiarize yourselves with
• TD GFD checklist
• New Target Drug GFD policy
• Talking points for patients and prescribers
• Ensure all stores have a "refused" folder
- Ensure staff is notifying DEA for every prescription they refuse to fill (not just fake/forged rx's)
• Communicate to your stores for an ASAP start
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Additional Questions?

- Wait until all questions are submitted and put into one email
- Email: Tasha.Polster@walgreens.com
- All questions will be answered and communicated together

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Follow Up

- Keep notes of feedback of what's working, what's not working
- On store visits, review filled CII prescriptions for documentation as well as the refusal folder for documentation
- Another conference call will be scheduled with for feedback

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